ARC 3228C

PHARMACY BOARD[657]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)*"b."*

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 16, "Nuclear Pharmacy Practice," Iowa Administrative Code.

The amendments were approved at the June 28, 2017, regular meeting of the Board of Pharmacy.

Pursuant to Iowa Code section 17A.7(2), the Board has conducted on overall review of this chapter of administrative rules. The Board preemptively sought comments and suggestions from those in the field of nuclear pharmacy in identifying the amendments. The proposed amendments provide alignment with the Iowa Department of Public Health and the Nuclear Regulatory Commission with respect to definitions and training requirements for authorized nuclear pharmacists. The amendments also clarify the type of license issued to nuclear pharmacies and incorporate federal minimum standards for sterile compounding, consistent with other rule making by the Board.

Any interested person may present written comments, data, views, and arguments on the proposed amendments not later than 4:30 p.m. on August 22, 2017. Such written materials may be sent to Terry Witkowski, Executive Officer, Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or by e-mail to terry.witkowski@iowa.gov.

Requests for waiver or variance of the discretionary provisions of Board rules will be considered pursuant to 657—Chapter 34.

After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement Iowa Code section 155A.13.

The following amendments are proposed.

ITEM 1. Amend rule 657—16.1(155A) as follows:

657—16.1(155A) Purpose and scope. ~~It is unlawful to receive, possess or transfer radioactive drugs except in accordance with the provisions of Iowa Code chapter 155A. It is also unlawful for any person to provide radiopharmaceutical services unless the person is a pharmacist or a person acting under the direct supervision of a pharmacist acting in accordance with the provisions of Iowa Code chapter 155A, board rules and rules of the environmental protection commission. It is not unlawful for a medical practitioner to receive, possess, or transfer radioactive drugs for administration to patients as provided in Iowa Code chapter 148. No person may receive, acquire, possess, use, transfer, or dispose of any radioactive material except in accordance with the conditions set forth by the environmental protection commission pursuant to the provisions of Iowa Code chapter 455B. The requirements of these nuclear pharmacy rules are in addition to and not in substitution for 657—Chapter 8 and other applicable provisions of rules of the board and the environmental protection commission or the public health department.~~ This chapter establishes the minimum standard for the practice of pharmacy relating to radiopharmaceutical drugs. These rules apply to individuals authorized to receive, handle, transfer, dispense, or dispose of radiopharmaceutical drugs pursuant to Iowa Code chapters 155A, 148, and 455B, and rules of the board, the environmental protection commission, or the public health department. For pharmacies, these rules are in addition to other applicable chapters of rules of the board including, but not limited to, 657—Chapters 8 and 20.

ITEM 2. Amend rule **657—16.2(155A)**, definition of "Board," as follows:

"Board" means the Iowa board of pharmacy ~~examiners~~.

ITEM 3. Amend rule **657—16.2(155A)**, definition of "Qualified nuclear pharmacist," as follows:

"~~Qualified~~ Authorized nuclear pharmacist" means a person currently licensed to practice pharmacy in Iowa who meets the qualifications established by rule 657—16.3(155A).

ITEM 4. Amend rule 657—16.3(155A) as follows:

657—16.3(155A) ~~General~~ Training requirements for ~~qualified~~ authorized nuclear pharmacist. ~~A qualified~~ An authorized nuclear pharmacist shall meet all requirements of ~~either alternative one or alternative two established in subrules 16.3(1) and 16.3(2), respectively~~ the United States Nuclear Regulatory Commission pursuant to federal regulations.

~~**16.3(1)** *Alternative one.* A qualified nuclear pharmacist shall:~~

~~*a.* Meet minimum standards of training for medical uses of radioactive materials; and~~

~~*b.* Be a currently licensed pharmacist in the state of Iowa; and~~

~~*c.* Submit an affidavit of experience and training to the board; and~~

~~*d.* Have completed one of the following nuclear pharmacy training alternatives:~~

~~(1) Received a minimum of 90 contact hours of didactic instruction in nuclear pharmacy from an accredited college of pharmacy. In addition, the pharmacist shall have attained a minimum of 160 hours of clinical nuclear pharmacy training under the supervision of a qualified nuclear pharmacist in a nuclear pharmacy that provides nuclear pharmacy services or in a structured clinical nuclear pharmacy training program of an accredited college of pharmacy.~~

~~(2) Successfully completed a nuclear pharmacy residency accredited by the American Society of Health-System Pharmacists (ASHP).~~

~~(3) Successfully completed a certificate program in nuclear pharmacy accredited by the Accreditation Council on Pharmaceutical Education (ACPE).~~

~~**16.3(2)** *Alternative two.* A qualified nuclear pharmacist shall:~~

~~*a.* Be a currently licensed pharmacist in the state of Iowa; and~~

~~*b.* Be certified by the Board of Pharmaceutical Specialties as a board-certified nuclear pharmacist (BCNP); and~~

~~*c.* Submit an affidavit of BCNP credentials to the board.~~

ITEM 5. Amend rule 657—16.4(155A) as follows:

657—16.4(155A) General requirements for ~~pharmacies~~ a pharmacy providing radiopharmaceutical services. A pharmacy providing radiopharmaceutical services shall obtain a limited use pharmacy license pursuant to rule 657—8.35(155A) prior to commencing provision of services in this state.

16.4(1) *~~Qualified~~ Authorized nuclear pharmacist.* ~~A license to operate a pharmacy providing radiopharmaceutical services shall be issued only to a qualified nuclear pharmacist who shall be the pharmacist in charge of the pharmacy.~~ The pharmacist in charge shall be an authorized nuclear pharmacist and shall be responsible for, at a minimum, the requirements in rule ~~657—6.2(155A)~~ 657—8.3(155A). All personnel performing tasks in the preparation and distribution of radioactive drugs shall be under the direct personal supervision of ~~a qualified~~ an authorized nuclear pharmacist. ~~A qualified~~ An authorized nuclear pharmacist is responsible for all operations of the pharmacy and, except in emergency situations, shall be in personal attendance at all times that the pharmacy is open for business.

16.4(2) *Space requirements.* Nuclear pharmacies shall have adequate space, commensurate with the scope of services required and provided. The nuclear pharmacy area shall be separate from the pharmacy areas for nonradioactive drugs and shall be secured from unauthorized personnel. All pharmacies handling radiopharmaceuticals shall provide a radioactive storage and product decay area, occupying at least 25 square feet of space, separate from and exclusive of the ~~hot laboratory,~~ drug compounding, dispensing, quality assurance, and office areas.

16.4(3) to **16.4(9)** No change.

16.4(10) *Radioactivity.* The amount of radioactivity for ~~each individual preparation~~ a radiopharmaceutical prepared by a nuclear pharmacy shall be determined by radiometric methods immediately prior to dispensing.

16.4(11) *Redistribution.* ~~A~~ When a nuclear pharmacy ~~may redistribute~~ distributes to another ~~nuclear pharmacy or authorized party~~ entity radioactive drugs that are ~~the subject of an approved new drug application if~~ FDA-approved, commercially manufactured drug products, the pharmacy ~~does~~ shall not process the radioactive drugs in any manner or violate the product packaging.

ITEM 6. Amend rule 657—16.6(155A) as follows:

657—16.6(155A) Minimum equipment requirements. Each nuclear pharmacy shall maintain the following equipment for use in the provision of radiopharmaceutical services:

1. Laminar flow hood;
2. Dose calibrator;
3. Refrigerator;
4. Single-channel scintillation counter;
5. Microscope;
~~6. Autoclave, or access to one;~~
~~7.~~ 6. Incubator, or access to one;
~~8.~~ 7. Radiation survey meter;
~~9.~~ 8. Other equipment necessary for the radiopharmaceutical services provided as required by the board.

A pharmacy may request waiver or variance from a provision of this rule pursuant to the procedures and requirements of 657—Chapter 34.

ITEM 7. Adopt the following **new** rule 657—16.8(155A):

657—16.8(155A) Sterile radiopharmaceutical preparations and compounding. Sterile radiopharmaceutical preparations shall comply with federal laws and regulations for radiopharmaceuticals, including enforceable chapters of the United States Pharmacopeia (USP) and final guidance documents regarding sections of the Federal Food, Drug, and Cosmetic Act.